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No. 87-1214

In the Supreme Court of the United States

OCTOBER TERM, 1987

NATIONAL COTTONSEED PRODUCTS ASSOCIATION,
PETITIONER

v.

ANN McLAUGHLIN, SECRETARY OF LABOR, ET AL.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT*

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the Occupational Safety and Health Administration's cotton dust standard properly requires monitoring and medical testing of cottonseed processing employees, in order to protect the health of especially susceptible employees and to check the accuracy of the risk assumptions underlying removal of a longstanding exposure limit.



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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-23a) is reported at 825 F.2d 482. The Secretary of Labor's amended cotton dust standard and statement of reasons in support of the regulation appear at 50 Fed. Reg. 51120-51179 (1985).

JURISDICTION

The judgment of the court of appeals (Pet. App. 24a-25a) was entered on August 7, 1987. A timely petition for rehearing, with suggestion of rehearing en banc, was denied on October 23, 1987 (Pet. App. 26a-27a). The petition for a writ of certiorari was filed on January 20, 1988. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

(1)

STATEMENT

1. The Occupational Safety and Health Act of 1970, 29 U.S.C. 651 *et seq.* (the Act), empowers the Secretary of Labor to adopt occupational safety and health standards, which are defined by Section 3(8) of the Act as requirements "reasonably necessary or appropriate to provide safe or healthful employment and places of employment" (29 U.S.C. 652(8)). Section 6(a) required the Secretary, within two years of the Act's enactment and without formal rulemaking proceedings, to adopt as occupational safety or health standards existing "national consensus" or "established Federal standards" (29 U.S.C. 655(a)). In addition, Section 6(b) of the Act authorizes the Secretary to promulgate, modify or revoke standards, through notice and comment rulemaking (29 U.S.C. 655(b)). Whenever a rule promulgated pursuant to Section 6(b)(8) "differs substantially from an existing national consensus standard," the Secretary must set forth in the Federal Register the reasons the rule adopted will "better effectuate the purposes of" the Act (29 U.S.C. 655(b)(8)). Section 6(b)(5) requires that in regulating exposure to "toxic materials or harmful physical agents," the Secretary must promulgate the standard which, "on the basis of the best available evidence," will provide the greatest level of protection feasible (29 U.S.C. 655(b)(5)). Where appropriate, standards also "shall prescribe * * * medical examinations or other tests" at employers' expense, "in order to most effectively determine whether the health of * * * employees is adversely affected by * * * exposure" to a regulated hazard (29 U.S.C. 655(b)(7)).

2. In 1971, pursuant to Section 6(a), the Secretary adopted the standard established under the Walsh-Healey Act, 41 U.S.C. 35(e), of 1000 ug/m³ (micrograms per cubic meter) as the industry-wide standard governing ex-

posure to airborne concentrations of cotton dust (Pet. App. 3a). In 1976, the Occupational Safety and Health Administration (OSHA) announced its intention to promulgate a permanent Section 6(b) cotton dust standard (41 Fed. Reg. 56498), and after amassing a voluminous record, published a final rule in 1978 covering all aspects of cotton dust exposure in textile and non-textile industries (43 Fed. Reg. 27350).¹ For the cottonseed processing industry, in which petitioner's members are engaged, the 1978 standard prescribed a permissible exposure limit (PEL) of 500 ug/m³ and required cottonseed oil mills to institute medical surveillance programs, providing for initial placement and annual medical screening of employees (Pet. App. 3a).²

This standard never took effect for cottonseed processing and other non-textile industries, however, because of litigation before the court of appeals and this Court. *AFL-CIO v. Marshall*, 617 F.2d 636 (D.C. Cir. 1979), aff'd in part and vacated in part *sub nom. American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490 (1981).³ Accordingly, the cottonseed processing industry has remained continuously subject to the Section 6(a) PEL of 1000 ug/m³ (Pet. App. 3a).

¹ The toxic nature of cotton dust, its acute and chronic effects on pulmonary function, and the history of its regulation are fully discussed in *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490 (1981).

² Cottonseed processing involves breaking down untreated cottonseed into linters (coarse fuzz) and seed hulls and kernels. The process is dusty and the linters contain contaminants similar to those in baled cotton fiber. After cleaning, linters are baled and the seed remnants are used to produce cottonseed oil and meal. 43 Fed. Reg. 27350, 27369 (1978).

³ The court of appeals remanded the record for cottonseed processing only for reconsideration of the standard's economic feasibility. *AFL-CIO v. Marshall*, 617 F.2d at 669. Thereafter, when this Court remanded the other non-textile segments for reconsideration in light of *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607

On remand from the litigation, the Secretary reviewed a number of cross-sectional health studies of American and foreign cottonseed processing workers, as well as medical expert testimony regarding health risks and protective measures (Pet. App. 7a; 50 Fed. Reg. 51133-51137 (1985); 48 Fed. Reg. 26966-26967 (1983)). The studies of domestic cottonseed workers uniformly demonstrated that a number of cottonseed workers manifest impaired lung function at current levels of cotton dust exposure in cottonseed oil mills, which is especially linked to length of employment, exposure at early steps of processing, general and specific allergies, and smoking (Pet. App. 7a; 50 Fed. Reg. 51133-51134 (1985)). There was, however, no affirmative evidence of increased prevalences of byssinosis,⁴ or of a dose-response relationship at current exposure levels (*ibid.*). Studies of foreign cottonseed workers, however, showed increased prevalences of byssinosis and other chronic lung disease at very high exposure levels (Pet. App. 7a, 8a; 50 Fed. Reg. 51133, 51135 (1985)). All medical experts agreed that the dust in cottonseed oil mills is not a "mere nuisance," but rather has "some biologic activity of a kind similar to that found in cotton textile mills" (Pet. App. 7a; 50 Fed. Reg. 51134-51135 (1985) (citation omitted)). These experts unanimously recommended medical surveillance of those working in the cottonseed industry to protect the health of especially susceptible workers and to develop an appropriate evidentiary

(1980), see *Cotton Warehouse Ass'n v. Marshall*, 449 U.S. 809 (1980), the Secretary undertook a similar review for cottonseed processing too.

⁴ Byssinosis, also known as "brown lung" disease, is a respiratory ailment characterized by coughing, breathlessness or tightness of the chest. See 50 Fed. Reg. 51125 (1985).

base for making an accurate assessment of true risk (Pet. App. 7a; 50 Fed. Reg. 51134 (1985)).⁵

Applying the significant risk analysis mandated by *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607 (1980) [hereinafter *Benzene*],⁶ the Secretary found that there was "not sufficient evidence of significant risk [within the cottonseed industry] which could be substantially reduced by lowering exposure limits" (50 Fed. Reg. 51135 (1985)). The Secretary therefore declined to establish a new, lower Section 6(b) exposure limit (*ibid.*). Similarly, the Secretary concluded from the same evidence that removal of the existing Section 6(a) PEL would not lead to significant health risk (50 Fed. Reg. 51136 (1985)).

The Secretary concluded, however, that he could find no significant risk in removing the existing PEL only if a "backstop" program of medical monitoring of employees was retained, in order to assess the correctness of that judgment and to protect unusually susceptible workers (50 Fed. Reg. 51135-51136 (1985)). Accordingly, the Secretary imposed on the industry the medical surveillance and related recordkeeping requirements of the cotton dust standard.⁷ The Secretary found direct support for this

⁵ One expert stressed that the true risk for cottonseed workers may be underestimated by the large cross-sectional studies in the record (50 Fed. Reg. 51133-51134 (1985)). He noted that medical surveillance would provide the type of longitudinal data necessary to make an accurate assumption about the real level of risk in cottonseed oil mills (*ibid.*).

⁶ The Secretary described his analytical approach to the significant risk analysis, including the factors to be taken into account in making rational policy judgments regarding risk, at 50 Fed. Reg. 51131 (1985).

⁷ These provisions, set out at 29 C.F.R. 1910.1043(h)(2) and (k)(2)-(4), require employers to provide initial placement medical screening, followed by routine screening every two years, except for

action in a passage in *Benzene* (448 U.S. at 657-658), where this Court approved in dictum "a backstop in the form of monitoring and medical testing," imposed in conjunction with standards set at exposure levels below those of significant risk. Such monitoring allows OSHA to "keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if it was initially set too high" and to "ensure that workers who were unusually susceptible * * * could be removed from exposure before they had suffered any permanent damage" (50 Fed. Reg. 51135 (1985) (quoting 448 U.S. at 658)).

This dictum applied here, the Secretary explained, because the decision to remove exposure limits was based on less-than-perfect evidence and two of the reasons cited by *Benzene* for a medical surveillance backstop were directly implicated by the record. Specifically, a backstop was necessary to "check on the validity of the assumption[]" that deregulation would not lead to significant health risks, since exposures might rise after the PEL was removed and the foreign studies showed an increased incidence of chronic lung disease at higher exposure levels, and thus an affirmative dose-response relationship (50 Fed. Reg. 51135 (1985)). Moreover, there was a clear medical need for such monitoring to identify and protect especially susceptible workers who, even at current exposure levels, had been shown to be at risk (*id.* at 51136). Accordingly, the Secretary determined not to exempt the

those employees as to whom the results of testing indicate that more regular testing (*i.e.*, every six months) is appropriate. The tests include completion of a prescribed questionnaire; objective pulmonary function tests; and completion of a physician's report containing specified information. The recordkeeping requirements of Section 1910.1043(k)(2)-(4) are keyed to these medical screening provisions.

cottonseed processing industry from the medical surveillance requirements of the cotton dust standard.

3. Petitioner National Cottonseed Products Association sought review, pursuant to 29 U.S.C. 655(f), of the cotton dust standard as it applies to the cottonseed processing industry. The court of appeals upheld the medical surveillance requirements as “sanction[ed]” by “an unusually precise dictum in *Benzene*” (Pet. App. 4a). The court explained that the *Benzene* Court specifically addressed the Secretary’s regulatory options where she is “uncertain whether the residual risk [at the selected exposure level is] significant” (*id.* at 6a). In such circumstances, the Secretary has authority, as explained in *Benzene*, to require backstop employee health monitoring to check the validity of the assumptions regarding the exposure limit selected, to develop sound evidence for changing the exposure limit, and to “ensure that unusually susceptible workers could be removed from exposure before they suffered permanent damage” (*ibid.*, citing *Benzene*, 448 U.S. at 657-658). Thus, *Benzene* permits “backstop monitoring” where the “‘less-than-perfect’” evidence upon which OSHA relies “indicates * * * a real possibility of significant health risks under the other aspects of the standard adopted (here, no regulation at all)” (Pet. App. 8a).

The court also found the evidence in the rulemaking record sufficient to “invoke the conditions suggested by * * * *Benzene* for a backstop monitoring requirement” (Pet. App. 8a). The studies of cottonseed workers and experts’ testimony disclosed that, at existing exposure levels, domestic cottonseed workers as a group suffer from decreased lung function, even though they do not experience an increased incidence of byssinosis (*id.* at 7a). And a subset of hypersensitive workers suffer from

respiratory ailments (*id.* at 4a, 7a). Moreover, foreign cottonseed workers subject to higher doses than domestic workers experience significant health effects, suggesting a dose-response relationship (*id.* at 7a). Thus, the Secretary appropriately concluded that "the risk of material harm to cottonseed workers would not be 'significant' even without a PEL, so long as medical surveillance was retained as a 'backstop' " (*id.* at 4a (quotation in original)).

Responding to petitioner's argument that medical surveillance may be required only where OSHA identifies some " 'reasonably attainable level' " at which harm will occur, the court of appeals noted that OSHA was hampered in making such a determination here because of the "ambiguous relation between reality and the pre-existing regulation" (Pet. App. 6a).⁸ The court of appeals concluded, however, that application of the *Benzene* dictum was justified by the evidence of risk before OSHA, from which it reasonably inferred that exposures might rise, to the detriment of worker health, with the removal of exposure limits (*id.* at 6a-7a). The court agreed with the Secretary that under these circumstances, medical surveillance was necessary both to protect worker health and to provide an evidentiary basis for assessing the validity of the assumptions upon which OSHA relied in eliminating the PEL.⁹

⁸ The court noted general agreement that the cottonseed industry "has not complied with the 1000 ug/m³" PEL, but stressed that "there is no concession that the regulations of the past 16 years have been absolutely without effect," and that one study found that 16 of 18 mills maintained mean exposure levels at or below the PEL (Pet. App. 6a).

⁹ The court also rejected petitioner's claims that compliance with the medical surveillance requirements is not technologically or economically feasible for the industry. Petitioner does not seek review of this aspect of the court's ruling, although it asserts that medical surveillance is costly and inconvenient (Pet. 14). The court of appeals

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or of any other court of appeals. Accordingly, the petition for a writ of certiorari should be denied.

1. The court below correctly held that the Secretary's decision to require "backstop" medical surveillance of cottonseed industry workers falls squarely within an "unusually precise" dictum in the *Benzene* decision. The central thrust of the pertinent passage (448 U.S. at 657-658) is that backstop monitoring may be required even at exposure levels with respect to which no significant risk is shown. To justify such "backstop" monitoring, the Secretary must reasonably conclude, based on the best available evidence, that there is residual risk at those lower exposure levels which warrants prophylactic regulatory action. See 448 U.S. at 657-658. As the court of appeals held, the Secretary properly found that the rulemaking record invoked precisely the same conditions identified in *Benzene* as warranting backstop monitoring.¹⁰

First, as the court found, the record conclusively established a class of unusually susceptible cottonseed

upheld OSHA's conclusion that the costs of compliance here with the medical surveillance requirements were minuscule (slightly over \$70,000 annually, or less than 0.01% of the industry's annual gross revenues of \$777.6 million), finding that any errors made by OSHA in its cost analysis were "trivial" and inconsequential (Pet. App. 11a-12a).

¹⁰ Section 6(f) of the Act, 29 U.S.C. 655(f), prescribes "substantial evidence" review of the Secretary's determinations. The court below carefully reviewed the evidence upon which the Secretary had relied in this case, as well as contradictory evidence in the record, and found the evidence supported the medical surveillance standard. Petitioner does not challenge the court's decision on substantial evidence grounds.

workers who suffered impaired lung function even at current levels of cotton dust exposure. As in *Benzene*, medical surveillance would protect their health by permitting their removal from exposure. See Pet. App. 6a; compare 50 Fed. Reg. 51135-51136 (1985) (monitoring allows removal of unusually susceptible persons from particularly dusty jobs); *Benzene*, 448 U.S. at 658 (footnote omitted) (monitoring "could ensure that workers who were unusually susceptible to benzene could be removed from exposure before they had suffered any permanent damage").¹¹

The record also demonstrated clear increased prevalences of byssinosis and other chronic lung diseases among workers in foreign cottonseed oil mills, where exposure levels are higher. Given the real possibility that exposures in American cottonseed mills might rise with the removal of the Section 6(a) PEL,¹² backstop monitoring

¹¹ Numerous decisions uphold the imposition of medical testing and other remedial requirements at action levels lower than established exposure limits, in order to protect especially susceptible workers. See, e.g., *GAF Corp. v. Occupational Safety & Health Review Comm'n*, 561 F.2d 913 (D.C. Cir. 1977) (cited approvingly in the *Benzene* discussion of backstop surveillance, upholding the requirement of medical examinations for employees exposed to *any* airborne concentrations of asbestos); *Forging Indus. Ass'n v. Secretary of Labor*, 773 F.2d 1436, 1443-1444 (4th Cir. 1985) (en banc) (upholding hearing conservation amendment to noise exposure standard, providing for testing and appropriate follow-up measures, as needed, for employees exposed to noise levels at action levels below the PEL); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1237 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (upholding the medical removal provisions of the lead standard, keyed to the results of medical surveillance and biological monitoring of employees exposed to lead concentrations significantly lower than the PEL).

¹² Petitioner argues (Pet. 14) that industry was not in compliance with the existing PEL, and thus that it was unreasonable to assume

was necessary to check the validity of the basic assumption that elimination of the PEL would not give rise to significant risk. There is thus no merit to petitioner's contention (Pet. 12-13) that the court below sanctioned impermissible employer-financed data gathering of merely possible health risks. See Pet. App. 7a; 50 Fed. Reg. 51136 (1985) (medical surveillance "provide[s] a backstop if [OSHA's] judgment [on significant risk] is incorrect"); *Benzene*, 448 U.S. at 658 (footnote omitted) (OSHA "could keep a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary basis for decreasing the limit if * * * initially set too high"). This Court specifically approved this "type of information-gathering" as contemplated by Section 6(b)(7), "which empowers the Secretary to require medical examinations to be furnished to employees exposed to certain hazards and *potential hazards*, 'in order to most effectively determine' " whether worker health is adversely affected by such exposure. *Benzene*, 448 U.S. at 658 n. 66 (citations omitted; emphasis added). Thus, the Secretary properly concluded that significant risk would not result from removal of the Section 6(a) PEL only if conditioned on backstop medical surveillance.¹³ In these

that elimination of the PEL might lead to material health impairment. The court of appeals correctly rejected this argument, stressing that because "there is no concession that the regulations of the past 16 years have been absolutely without effect," and, in fact, some record evidence reflects substantial compliance, the Secretary could "fairly infer" that removal of the PEL could result in increased exposure (Pet. App. 6a).

¹³ Seizing on the precise fact situation described in *Benzene*, petitioner argues that the dictum must be read in exceedingly literal fashion, and that backstop monitoring may only be imposed as an adjunct to a PEL or at levels at which significant risk is identified (Pet. 10-11). The court of appeals rightly rejected this constrained ap-

circumstances, the court of appeals correctly held that *Benzene*'s "unusually precise dictum" specifically sanctions the backstop medical surveillance standard imposed on the cottonseed industry in this case.¹⁴

2. Nor does the decision of the court below conflict with *Texas Independent Giners Ass'n v. Marshall*, 630 F.2d 398 (5th Cir. 1980), as petitioner asserts (Pet. 11-12). First, the nature of the regulatory actions and their stated justifications are quite different. The cotton ginning standard imposed a number of work practices and other protective measures in addition to medical testing.¹⁵ See 630 F.2d at 402-403. The Secretary rested the standard's requirements on a finding of health hazards at existing unregulated exposure levels. The Fifth Circuit rejected the standard in its entirety because it concluded that the Secretary's finding — characterized as "OSHA's finding of

proach, which would effectively rob the dictum of its meaning. As the court of appeals noted, this Court plainly did not confine backstop monitoring to the precise facts of its hypothetical, nor is there any sound reason to do so. Rather, the court of appeals correctly recognized that deleting an exposure limit, like lowering or raising a limit, is a regulatory judgment with respect to which imposition of medical surveillance as a backstop may be appropriate (Pet. App. 8a).

¹⁴ Petitioner erroneously argues (Pet. 11) that this Court would have upheld the medical surveillance requirements in *Benzene* if it believed that medical surveillance could be imposed in the absence of a PEL. But this Court specifically noted in *Benzene* that it was dealing only with the exposure limits set by the Secretary, and declined to rule on any other aspects of the standard. See, e.g., 448 U.S. at 630 n.30.

¹⁵ In addition to medical surveillance, the cotton ginning standard required work practice plans to minimize employee exposure to cotton dust; employee training programs; provision of disposable respirator masks to all employees desiring them and air powered air purifying respirators to certain other employees; and posting of workplace warnings regarding the dangers of cotton dust. See 43 Fed. Reg. 27418 (1978); *Giners*, 630 F.2d at 402-403.

a significant risk of a material health impairment" (*id.* at 407)—was not based on substantial evidence but rather on “assumptions without an adequate evidentiary basis” (*id.* at 409). The Fifth Circuit nowhere discussed or even alluded to the circumstances under which the Secretary may require medical surveillance as a backstop to permitted exposure at levels with respect to which no significant risk is shown. This omission is understandable since the Secretary did not justify the requirement on “backstop” grounds either in rulemaking or in the court of appeals.¹⁶

Ginners is also distinguishable from the decision below, because, as the Fifth Circuit noted, “the 1971 [Section 6(a)] PEL never applied to the ginning industry * * *” (630 F.2d at 403 n.20), and thus the case did not implicate the provision of the Act which permits modification or revocation of a Section 6(a) standard only if “the rule as adopted will better effectuate the purposes” of the Act (29 U.S.C. 655(b)(8)). By contrast, the cottonseed industry has been continuously subject to the Section 6(a) PEL. Thus, to eliminate the Section 6(a) PEL applicable to the cottonseed industry, the Secretary was obligated to find that the evidence “affirmatively indicate[s]” that significant risk is “unlikely to exist” at exposures likely to prevail *after* the PEL was eliminated. See 50 Fed. Reg. 51132 (1985). As explained above, the Secretary determined that this judgment could be made if, and only if, conditioned on the availability of backstop medical surveillance. No PEL, combined with medical surveillance, results in both considerable savings to the industry and protection for highly susceptible workers and reevaluation of risk, thus better effectuating the Act’s goal of protecting employee health. See *id.* at 51135-51136. In *Ginners*, on the other hand, the

¹⁶ *Ginners* was briefed and argued before *Benzene* was decided, even though it was issued shortly after *Benzene*.

court had no occasion to consider the circumstances under which a Section 6(a) exposure limit could properly be revoked or the link between revocation of a Section 6(a) limit and retention of medical monitoring as a backstop to that determination.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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